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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,498	11/26/2003	Patrick D. Mize	245977US	6221
22850	7590	05/02/2006	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			LEITH, PATRICIA A	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/721,498

Applicant(s)

MIZE, PATRICK D.

Examiner

Patricia Leith

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 27-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/25/05</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

The Examiner in this case has changed. Please note the new communication information at the bottom of this Office Action.

Claims 27-36 are pending in the application and were examined on their merits.

Terminal Disclaimer

The terminal disclaimer filed on 3/16/05 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US patent 6,680,177 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hemker et al. (WO 92/07954) in view of Oberhardt (US 5,110,727).

Hemker et al. (WO 92/07954) taught basic assay methods for determination of anticoagulants such as low molecular weight heparin LMWH. Specifically, Hemker et al. taught that LMWH was determined via measuring thrombin formation upon addition of plasma with an assay reagent comprising factor X, prothrombin, phospholipids and chromozym, and an activator reagent comprising factor IXa (see entire reference, especially Examples 1 and 2). It is noted that factor IXa is a factor Xa activator as required by the claims.

Hemker et al. did not specifically teach wherein the assay reagent was a dry reagent, or wherein the dry reagent was present in a kit form further described by wherein the assay reagent is 'arranged in a substantially flattened format and containing magnetic particles distributed substantially homogeneously there through', or wherein the kit further comprised a transfer pipette, a timing means, or wherein said element comprises a channel structure defining a sample well and reaction volume in fluid communication with each other, said channel structure having a geometry causing a liquid sample placed in said sample well to be drawn into and filling said reaction volume via capillary action.

Oberhardt (US 5,110,727) disclosed an accurate, rapid, one-step coagulation kit which included a dry reagent coupled with magnetic beads on a dry test strip ('substantially flat surface') wherein said magnetic beads, upon contact with a sample containing coagulation/anticoagulation factors, oscillate in a magnetic field, whereby the clotting parameters can easily be assessed (see for example, col. 3, line 56- col. 4, line 56- col. 4, line 32 and col. 10, lines 39-57). Oberhardt additionally teaches that the kit includes a transfer pipette, made 'essentially of nonthrombogenic material' in order to obtain a blood sample and transfer the blood sample to the dry reagent for analysis (Again, please see col. 10, lines 39-57). Oberhardt clearly teaches how to make a dry reagent from a liquid reagent; which entails simply freeze drying a liquid reagent on a flat slide (see Col. 46, lines 32-45). Oberhardt also teaches that the reagent kit is "suitable for performing a whole blood coagulation assay, said channel structure having a geometry causing a blood sample placed in said sample well to be drawn into and filling said reaction volume via capillary action" (see claim 52 for example).

Oberhardt, propounding on the benefits of using this type of one-step reagent system states that "Although the one stage method has longer reaction times, the overall test time is shorter, since the 5 minute incubation step was not necessary. The one stage test is also simpler to perform"

One of ordinary skill in the art would have been motivated to combine the reagent assay as taught by Hemker et al. with the reagent assay system as disclosed by Oberhardt in order to create an anti-coagulant assay system which was clearly more rapid. The ordinary artisan would have easily recognized that the assay for LMWH could have easily been modified for use in the dry reagent/magnetic bead clotting assay system in order to gain a more rapid response. This rapid response would have been quite advantageous especially in clinical settings where patient's clotting information is often needed urgently.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Thursday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1655

A handwritten signature in black ink, appearing to read 'Patricia Leith', with a stylized, flowing script.

February 21, 2006